



4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2017-0116]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny applications from two individuals treated with Implantable Cardioverter Defibrillators (ICDs) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, S.E., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., e.t., Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> and/or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, S.E., Washington, DC, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to <http://www.regulations.gov>, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at <http://www.dot.gov/privacy>.

II. Background

On May 4, 2017, FMCSA published a FR notice (82 FR 20961) announcing receipt of applications from two individuals treated with ICDs and requested comments from the public. These two individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period closed on June 5, 2017, and two comments were received.

FMCSA has evaluated the eligibility of these applicants and concluded that granting these exemptions would not provide a level of safety that would be equivalent to or greater than, the level of safety that would be obtained by complying with the regulation 49 CFR

391.41(b)(4). A summary of each applicant's medical history related to their ICD exemption request was discussed in the May 4, 2017, Federal Register notice and will not be repeated in this notice.

In reaching the decision to deny these exemption requests, the Agency considered information from the Cardiovascular Medical Advisory Criteria, the April 2007 Evidence Report "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety, a December 2014 focused research report "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of the reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce. [Appendix A to Part 391-Medical Advisory Criteria, section D, paragraph 4]. The advisory criteria for 49 CFR 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. Implantable cardioverter defibrillators are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received two comments in this proceeding. Each of the comments was favorable towards the applicants continuing to drive CMV's with ICD's citing their ICDs have not deployed and their medical and physical conditions are stable. FMCSA acknowledges the commenters' responses concerning stable medical histories with ICDs. Based on the available medical literature cited above, however, FMCSA believes that a driver with an ICD is at risk for incapacitation if the device discharges. This risk is combined with the risks associated with the underlying cardiovascular condition for which the ICD has been implanted as a primary or secondary preventive measure.

IV. Basis for Exemption Determination

Under 49 U.S.C.31136(e)and 31315, FMCSA may grant an exemption if it finds such an exemption would likely achieve a level of safety that is equivalent to, or greater then, the level that would be achieved absent such an exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of each applicant's medical information provided by the applicant, available medical and scientific data concerning ICDs, and public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope (a transient loss of consciousness) or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. See the April 2007 Evidence Report on Cardiovascular Disease and Commercial Motor vehicle Driver Safety, April 2007.¹ A focused research report on Implantable Cardioverter Defibrillators and the Impact of a Shock on a Patient When Deployed completed for the FMCSA December 2014 indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety and upholds the findings of the April 2007 report.

V. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety

¹ Now available at http://ntl.bts.gov/lib/30000/30100/30123/Final_CVD_Evidence_Report_v2.pdf

maintained without the exemption. Therefore, the following two applicants have been denied exemptions from the physical qualification standards in 49 CFR 391.41(b)(4):

Justin D. Dale (IA)

Raymond M. Loffredo (PA)

Each applicant has, prior to this notice, received a letter of final disposition regarding his/her exemption request. Those decision letters fully outlined the basis for the denial and constitutes final action by the Agency. The list published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Issued on: January 5, 2018.

Larry W. Minor,

Associate Administrator for Policy.